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Research Article

ASSESSMENT OF SYMPTOMS, RISK FACTORS, PRESCRIBING PATTERNS AND QUALITY OF LIFE IN PEPTIC ULCER DISEASE AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Peptic ulcer disease is one of the most common diseases, affecting approximately 50% of the world population. *Helicobacter pylori* (*H. pylori*) infection, non-steroidal anti-inflammatory drugs (NSAIDs), and low-dose aspirin use are three independent and the most important modifiable risk factors. This study aims to assess the symptoms, risk factors, prescribing patterns and quality of life inpeptic ulcer disease in a tertiary care hospital. A prospective cross-sectional and observational study was conducted at Bhimavaram from June 2018 to December 2018. Details regarding the past medical history and medication history, symptoms, risk factor, prescribing patterns, current therapy were obtained by patient interview and by observing case notes and their quality of life were assessed by using Short form -36 questionnaires. Descriptive statistics of demographics included percentages, mean and standard deviation. Paired t-test was used for determining if there is any significance in the change detected before and after treatment. Out of 150 patients, 72.66% were males and the remaining 27.33% were females. Mean age was 42.95 ± 12.9 years. In the present study, risk for PUD was associated with H. pylori and NSAID's. Most commonly used drugs were esomeprazole based H.P kit. The response scores of all the questions in SF-36 questionnaire increased statistically, which indicates the improvement in Quality of life after treatment. The study concludes that *H. pylori* is the major risk factor and is effectively managed by using esomeprazole based triple therapy. Peptic ulcer invariably affects the quality of life of the affected individuals through changes in daily routine.

Keywords: Peptic ulcer disease, Risk factors, Prescribing patterns, Short form 36 questionnaire.

INTRODUCTION

Peptic ulcer disease (PUD), describes a condition in which there is a disruption in the entire thickness of the gastric or duodenal mucosa by resulting in a defect or excavation locally that persists as a result of acid and pepsin in the gastric juice results in presence of active inflammation.[1] These ulcers develop most often in the stomach, first part of the small intestine and occasionally in the lower esophagus.[2-4] PUD is of two types which include an ulcer in the stomach known as a gastric ulcer (GU) and that in the first part of the intestine known as a duodenal ulcer (DU).[3]

Peptic ulcers are present in 4% of the population[3]. The lifetime risk for developing a PUD is approximately 10%.[2-4] The prevalence is about 70% in developing countries and 40% in developed countries.[2] In India, the prevalence of *H. pylori* infection is about 80%, especially in rural areas.[1] Recent studies showed that *H. pylori* are present in more than 90% of patients with DU and approximately 70% of those with GU.[5] *H. pylori* are most commonly observed in the age group of 12-80 years. Duodenal ulcers in males are affected ten times as often as females.[2] Etiological factors of PUD include *H. pylori* infection, NSAIDs, pepsin, smoking, alcohol, bile acids, steroids and stress. Other causes include hyper-secretion of gastric acid, viral infections, vascular insufficiency, radiation, rare genetic subtypes and idiopathic. *H. pylori* are a gram-negative organism which was identified as a causative factor for ulcers in 1982 by Australian scientists Robin Warren and Barry J Marshal. In 2005; they were awarded Nobel Prize for their discovery of *H. pylori* and its role in gastritis and PUD. [2]

Symptoms observed in PUD are abdominal pain that is often epigastric and described as burning but also may present as vague discomfort, abdominal fullness or cramping, early satiety, pain or discomfort in the upper abdomen, loss of appetite and nocturnal pain that awakens from sleep. Other possible symptoms include bloody or dark tarry stools, chest pain, fatigue, belching, bloating, nausea associated with vomiting, weight loss and heartburn.[2-4] Complications of PUD include internal bleeding, obstruction, perforation and peritonitis.[3]

The diagnosis is mainly characterized by hallmark features. Routine laboratory tests are not helpful in establishing the diagnosis of uncomplicated PUD. Diagnosis of H. pylori infection can be made by two tests endoscopic tests and non-endoscopic tests.[2] There are two types of non-endoscopic tests: 1. Test that identifies active infection (e.g.: Breath test). 2. Tests that detect antibodies (e.g.: Stool test, Blood test). The endoscopic test gives a definitive diagnosis of PUD, it is invasive, more expensive, and usually requires a mucosal biopsy for histology, culture, or detection of urease activity. [1]

Anti-peptic ulcer drugs like PPIs, H_2 receptor antagonists, antacids, synthetic prostaglandins and cytoprotective agents are widely used.[6] Proton pump inhibitors are medications that reduce production of gastric acid, relieve peptic ulcer pain, and promote healing. The most commonly used PPIs are omeprazole, lansoprazole, pantoprazole, rabeprazole and esomeprazole. Among these esomeprazole provides better control of intragastric pH, producing higher healing rates and symptomatic control than any other PPIs. When combined with antibiotics, esomeprazole is more effective than other PPIs.[7] Histamine receptor antagonists

block the histamine which is a substance that stimulates acid production.[8]

The FDA approved treatment options include triple therapy, quadruple therapy, sequential therapy. Triple therapy: PPI standard dose (twice daily) plus clarithromycin 500 mg (twice daily) plus amoxicillin 1 g (twice daily) or metronidazole 500 mg (twice daily). Quadruple Therapy: PPI (standard dose twice daily) plus metronidazole 500 mg (3 times daily) plus tetracycline 500 mg (3 times daily) plus bismuth (dose depends on preparation) for 10 days. Sequential therapy: PPI (standard dose twice daily) plus amoxicillin 1 g (twice daily) for 5 days followed by PPI (standard dose twice daily) plus clarithromycin 500 mg (twice daily) plus tinidazole 500 mg (twice daily) for 5 days.[1] Non-pharmacological therapy in patients with PUD should eliminate or reduce stress, smoking, use of NSAIDs, avoid spicy foods and beverages.[2]

Quality of life (QOL) is often considered to be more important than the quantity of life. Patient's physical, mental, emotional and social status will also affect the QOL. Health care of not only patients but also the health status of the general public as well as the impact of health care intervention is increasingly assessed for QOL. One goal of the measurement of quality of life (QOL) is to have an objective evaluation of how and how much the disease influences the patient's life and how patients cope with it. Peptic ulcer invariably affects the QOL of the affected individuals in their daily routine and their work.[9]

To measure the quality of life of patients SF-36 questionnaire is used as a health survey tool. SF-36 is considered as basic health care measure and also used to assess physical aspects and psychosocial aspects of quality of life with great reliability and validity.[10]

Aim

To assess the symptoms, risk factors, prescribing patterns and quality of life inpeptic ulcer disease in a tertiary care hospital.

Objectives

- To assess the symptoms and risk factors for peptic ulcer disease
- To study the prescribing patterns in peptic ulcer disease
- To determine the quality of life in peptic ulcer patients

MATERIALS AND METHODS

This study was conducted in Neeladri hospitals, Juvvalapalem road, Bhimavaram, West Godavari district, Andhra Pradesh, India. It is a 50 bedded tertiary care hospital. This hospital provides primary and specialized health care facilities to people in and around Bhimavaram regarding various gastrointestinal and hepatic problems.

Study design

The study was a prospective cross-sectional and observational study.

Study period

The study was carried out over for six months from July 2018 to December 2018.

Source of data and materials

Method of collection of data:

- Patient interview
- Patient case note/prescription

Method of collection of material

- Patient health related quality of life documentation form (SF-36)
- Patient consent form
- Patient data collection form

Study criteria

Inclusion criteria

- Patients willing to participate in the study
- Patients of age > 18 years of either gender
- Patients those who are diagnosed with PUD and with two or more co-morbidities

Exclusion criteria

- Pediatrics
- Pregnancy and lactating women
- Patients who are not willing to participate in the study

Study procedure

Method of data collection

All procedures performed in human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was started after obtaining clearance from the institutional ethical committee. Informed consent was obtained from all individual participants included in the study. Patients who were coming to the hospital regarding the disease in the out-patient department were screened based on the inclusion and exclusion criteria. Subjects who met the inclusion criteria were enrolled for the study. Informed consent was obtained from the patient or attendees of the patients. Details regarding the past medical history, medications, current therapy, their quality of life by using questionnaires were obtained by patient interview and by observing case notes. Symptoms, risk factors and prescribing patterns of the patients were obtained by using data collection form and it was documented.

Assessment of health related quality of life

According to the study design, patient's health related quality of life was measured by using scale SF-36 for Peptic ulcer disease. Collection of patient heath related issues according to their quality of life was done by using appropriate questionnaires and assessed by using scores according to scale.

Statistical methods

The prescribing patterns of Anti Peptic ulcer disease treatment were evaluated. Descriptive statistics of demographic and clinical variables included percentages, mean and standard deviation. Mean scores before and after treatment and mean changes were calculated for the domains of SF-36. A paired t-test was used to determine if the change detected from pre and post treatment was

significant. The probability value of ≤ 0.05 was set as significant and ≤ 0.001 as highly significant. All statistical analysis was performed using SPSS statistical software, version 18.

RESULTS

Total of 150 patients were enrolled in the study. 72.66% were males and 27.33% were females. The patients from 18-70 years were enrolled and among them most of the patients were in the age group of 31-45 (38%), 46-60 (30.66%), 18-30 (21.33%) and > 60 (10%).

Figure 1 shows that out of 150 patients, risk factor of *H. pylori* is about 28.02%, NSAID's is about 23.62% followed by stress 13.73%, smoking/alcohol 13.18%, history of ulcers 9.89%, diet 6.59% and age 4.94%. *H. pylori* and NSAID's are the most common risk factors for the cause of peptic ulcer disease.
Figure 2 represents patients complaints which include abdominal pain (13.64%), nausea/vomiting (12.26%), loss of appetite (12.14%), belching (11.38%), burning sensation (10.63%), pain awaken from sleep (9.01%), bloating (7.25%) and also other minor complaints such as pain increases with diet (5.88%), irregular bowels (5.88%), loss of weight (5.13%), pain decreases with diet (4.25%) and watery stools(2.5%).

Table 1 shows that the Esomeprazole based H.P kit (12.21%) is most commonly prescribed for the patients with peptic ulcer disease. In-patients not prescribed with *H. pylori* kit, drotaverine plus mefenamic acid (11.09%), either pantoprazole plus domperidone or rabeprazole plus domperidone or ofloxacin plusornidazole (10.77%) are given followed by pepsin and diastase syrup (10.45%), sucralfate (10.45%), ondansetron (8.19%), lactulose (4.5%), iron supplements (3.53%), loperamide (2.57%) and multivitamins (2.09%).

Table 2 represents that the mean value of physical functioning before treatment is 750 and after treatment is 919.83. The difference in means is highly (statistically) significant (P = 0.0001). The mean energy/ fatigue pre-treatment are 234.93 and post-treatment are 346. The difference in means is highly (statistically) significant (P = 0.0001). The mean social functioning pre-treatment is 144.73 and post-treatment are 160.97. The difference in means is highly statistically significant (P = 0.0001). The mean pain score pre-treatment is 77.30 and post-treatment is 160.47. The difference in means is highly statistically significant (P = 0.0001). The mean general health score pre-treatment is 302 and post-treatment is 377.67. The difference in means is highly statistically significant (P = 0.0001). The mean health change pre-treatment is 36.16 and post-treatment is 75.67. The difference in means is highly statistically significant (P = 0.0001). This shows that there is an improvement in quality of lifepost-treatment. The response score of all scales increased significantly, which indicates the improvement in quality of life after treatment. The mean role limitation was due to physical health and role limitation was due to emotional problems pre-treatment and post-treatment are statistically insignificant.

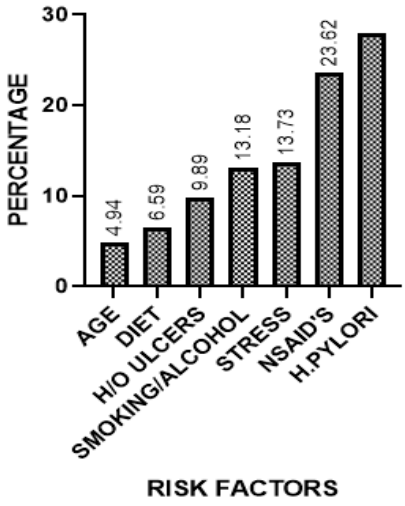

Figure 1: Distribution of study population based on risk factors

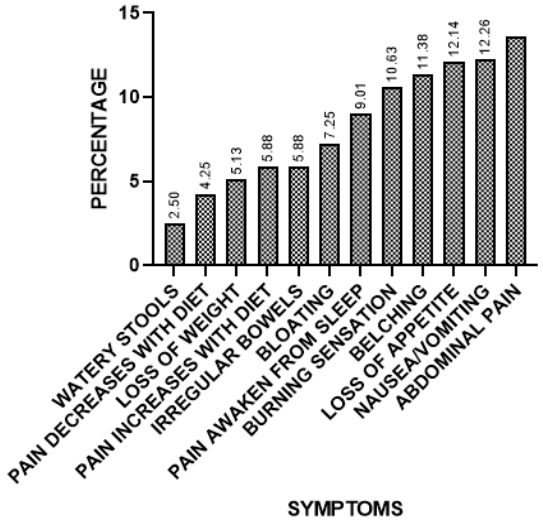

Figure 2: Prominent presenting complaints in study population

Table 1: Distribution of medications prescribed to the patients

S. No.	Drugs	Percentage
1	*H. pylori* kit	12.21
2	Drotaverine plus mefenamic acid	11.09
3	Ofloxacin plus ornidazole	10.77
4	Pepsin and diastase syrup	10.45
5	Sucralfate	10.45
6	Rabeprazole plus domperidone	10.77
7	Pantoprazole plus domperidone	10.77
8	Ondansetron	8.19
9	Lactulose	4.5
10	Iron supplements	3.53
11	Loperamide	2.57
12	Multivitamins	2.09

Table 2: Comparison of mean scores of SF-36 scales before and after treatment

SF36 SCALE (Q. No)	Treatment (n = 150)	Mean ± S.E.M	Significance -p Value
Physical functioning (Q: 3-12)	Before	750.00 ± 0.00	0.0001 (HS)
	After	919.83 ± 127.94	
Role limitation due to physical health (Q: 13-16)	Before	124.67 ± 185.34	0.729 (NS)
	After	363.33 ± 108.94	
Role limitation due to emotional problems (Q: 17-19)	Before	190.67 ± 144.40	0.080 (NS)
	After	260.5 ± 101.22	
Energy/Fatigue (Q:23,27,29,31)	Before	234.93 ± 36.65	0.0001 (HS)
	After	346.00 ± 33.88	
Emotional well being (Q: 34, 25, 26, 28, 30)	Before	406.13 ± 31.77	0.0001 (HS)
	After	437.80 ± 36.17	
Social functioning (Q:20,32)	Before	144.73 ± 30.29	0.0001 (HS)
	After	160.97 ± 27.11	
Pain (Q:21,22)	Before	77.30 ± 34.63	0.0001 (HS)
	After	160.47 ± 28.46	
General health (Q:1, 33-36)	Before	302.00 ± 45.93	0.0001 (HS)
	After	377.67 ± 49.25	
Health change (Q: 2)	Before	36.16 ± 17.51	0.0001 (HS)
	After	75.67 ± 15.58	

HS: Highly significant; NS: Non significant

DISCUSSION

The present study is done to assess the symptoms, risk factors, pharmacoepidemiology of the drugs to define the pattern of use, their availability in the hospital and to evaluate their impact on quality of life of patients in each prescription of Peptic ulcer disease OPD of a tertiary care hospital.

The total number of patients enrolled under this study group were (N = 150), the distribution of males (72.66%) is greater than females (27.33%). The observation co-relate with the findings of the study conducted by Jha KK *et al*., (2015) that males (55.75%) were found more than females (44.25%)[17].

The data of our study regarding risk factors of PUD showed that *H. pylori* (28.02%) is the major cause followed by prolonged use of NSAID's (23.62%), stress (13.73%) and smoking/alcohol (13.18%). In contrast to the present study, the study conducted by Shuhaib A *et al*. (2017) reported that there is a high risk for coffee consumption (81.8%), stress (77.3%), spicy food (57.6%), prolonged use of NSAID's (33.3%) and least by *H. pylori* (24.2%)[3].

Most patients presented with the complaint of abdominal pain (13.64%) and other complaints such as nausea/vomiting, loss of appetite, belching, burning sensation, pain awakens from sleep etc,. Similarly in the study conducted by Jayaram V *et al*., (2014) in Karnataka, patients presented with complaint of abdominal pain (64.2%), and the other complaints being nausea, vomiting, bloating and loss of appetite etc.[1]

The drugs prescribed for the treatment of PUD in our study are anti-*H. Pylori* drugs along with proton pump inhibitors. In patients who are not prescribed with *H. pylori* kit, PPIplusprokinetic, 1st generation cephalosporin and nitroimidazole combinations are prescribed followed by antispasmodics, probiotic and antiulcer protective. Our study shows that esomeprazole based *H. pylori* kit (12.21%) is most commonly prescribed. In patients who are not prescribed with *H. pylori* kit, drotaverine plus mefenamic acid (11.09%), pantoprazole plus domperidone or rabeprazole plus domperidone and ofloxacin plus ornidazole (10.77%) are given *H. pylori* kit and non *H. pylori* kit are prescribed based on the age, diet, occupation and severity of the disease, followed by pepsin and diastase syrup (10.45%), sucralfate (10.45%), ondansetron (8.19%), lactulose (4.5%), iron supplements (3.53%), loperamide (2.57%) and multivitamins (2.09%). The observation is in agreement with the findings reported by Jayaram V *et al*., 2014 in Karnataka in which 91% of the total patients were started on *H. pylori* kit, most common being Esomeprazole *H. pylori* kit (59.7%) followed by Pantoprazole *H. pylori* kit (31.3%)[1].

The observation of this study showed that the mean domain scores of physical functioning before treatment is 750 and after treatment is 919.83. The difference in means is highly statistically significant (P = 0.0001). The mean energy/ fatigue before treatment are 234.93 and after treatment are 346. The difference in means is highly statistically significant (P = 0.0001). The mean social functioning before treatment is 144.73 and after treatment are 160.97. The difference in means is highly statistically significant (P = 0.0001). The mean pain score before treatment is 77.30 and after treatment are 160.47. The difference in means is highly statistically significant (P = 0.0001). The mean general health score pre-treatment is 302 and post-treatment are 377.67. The difference in means is highly statistically significant (P = 0.0001). The mean health change pre-treatment is 36.16 and post-treatment is 75.67. The difference in means is highly statistically significant (P = 0.0001). This shows that there is an improvement in quality of life post-treatment. The response score of all scales increased significantly, which indicates the improvement in quality of life after treatment. The mean role limitation due to physical health and role limitation due to emotional problems before treatment and after treatment are statistically insignificant. A study conducted by Wen Z *et al*., (2014) stated that the role of patient-based symptoms and QoL assessment in evaluating and treating gastrointestinal disorders has increased. They found that patients with peptic ulcer disease had a lower quality of life with mean domain scores of physical functioning 82.2 ± 19.8, role limitation due to physical health problem 81.2 ± 33.6, bodily pain 81.5 ± 20.5, general health 56.7 ± 20.2, vitality 52.0 ± 20.9, Social functioning 83.0 ± 17.8, role limitation due to emotional problems 84.4 ± 32.4 and mental health 59.7 ± 22.7 compared to population norms. The mean scores for most domains and for the two component summaries were significantly different pre and post treatment. They experienced increased QoLpost-treatment[18].

CONCLUSION

The study finds the higher prevalence of PUD among males in general and in the age group of 31-45 specific. *H. pylori*, prolonged use of NSAID's, stress, smoking and alcohol were the reported risk factors among the studied population. It is strongly suggested that to create awareness regarding the nature of the disease and its risk factors. Abdominal pain, nausea/vomiting, belching, loss of appetite, burning sensation and pain awakens from sleep were the most commonly reported symptoms in the study population.

Esomeprazole based *H. pylori* kit was the most commonly prescribed drug among the patients for about 2 weeks. In patients who were not prescribed with *H. pylori* kit, drotaverine plus mefenamic acid, pantoprazole plus domperidone or rabeprazole plusdomperidone and ofloxacin plus ornidazole were given for about 10-15 days followed by pepsin and diastase syrup, sucralfate, and ondansetron. *H. pylori* kit and non *H. pylori* kit were prescribed on the basis of age, diet, occupation and severity of the disease. The current therapy strongly recommends the eradication of *H. pylori* in all patients with PUD, which result in cure for over 90% of the studied population. There was a statistical improvement in the health related quality of life in peptic ulcer patients by the course of treatment and self care. The study suggests that rational use of drugs results in the decrease of the symptoms to further improve the quality of life of the affected patients and comorbidities.

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